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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,158	01/30/2004	Inmaculada Silos-Santiago	MPI03-012P1RNOMNIM	6099

30405 7590 11/07/2005

MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/768,158	Applicant(s) SILOS-SANTIAGO ET AL.	
	Examiner Samuel W. Liu	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method of identifying a compound comprising combining the compound with a polypeptide, and detecting binding of the compound to said polypeptide, are classified in class 514, subclass 2.
- I. Claims 7-13, drawn to a method of identifying a compound comprising combining the compound with a host cell expressing polypeptide, and detecting binding of the compound to said polypeptide, are classified in class 514, subclass 2, and class 435, subclass 70.1.
- III. Claims 14-16, drawn to a method of identifying a subject having a pain comprising contacting a sample obtained from the subject comprising polypeptide, and detecting the presence of the polypeptide in said sample wherein said polypeptide binds a substance which interacts with said polypeptide, are classified in class 514, subclass 2, and class 435, subclass 7.1.
- IV. Claims 17-23, drawn to a method of treating a subject suffering from a pain characterized by aberrant polypeptide set forth in claim 17 comprising administering to said subject the polypeptide, are classified in class 514, subclass 2, and class 424, subclass 278.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and IV are directed to different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Invention I-IV since they constitute patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

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Additional Election

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed composition to which claims are restricted.

(i) If Group 1 or Group II is elected, applicant is required to elect one polypeptide from claim 1 and claim 8, respectively, because the polypeptides are structurally distinct from one another in length, composition and sequence, e.g., polypeptide 16386 (SEQ ID NO:2) consists of 284 amino acid residues while polypeptide 15402 (SEQ ID NO:4) consists of 356 amino acid residues and sequence of SEQ ID NO:2 is distinct from that of SEQ ID NO:4.

(ii) If Group III or Group IV is elected, applicant is required to elect one polypeptide from claim 14 (Group III) and claims 17 and 20-23 (Group IV), respectively, because the polypeptides in said each group are distinct/different in amino acid sequence and composition (see the above statement).

The response to the election requirement should also identify the claims readable thereon as directed to the elected invention.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 US 121 since the above-mentioned polypeptides are distinct/different from one another in amino acid sequence as well as amino acid composition, and thus, would be expected to exhibit different biological properties.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571) 272-09525. The fax phone numbers for the organization where this application or proceeding is

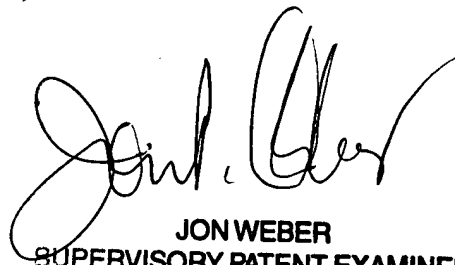
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assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.



Samuel W. Liu, Ph.D.

October 31, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER